UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

14-1361, -1366

IN RE BRCA1- AND BRCA2- BASED HEREDITARY CANCER TEST PATENT LITIGATION

UNIVERSITY OF UTAH RESEARCH FOUNDATION, THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA, HSC RESEARCH AND DEVELOPMENT LIMITED PARTNERSHIP, ENDORECHERCHE, INC., AND MYRIAD GENETICS, INC.

Plaintiffs-Appellants,

v.

AMBRY GENETICS CORPORATION,

Defendant-Appellee,

Appeal from the United States District Court for the Central District of Utah in consolidated case no. 2:13-cv-00640, Judge Robert J. Shelby.

APPELLANTS' MOTION TO EXPEDITE APPEAL

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UNIVERSITY OF UTAH, et al. v. AMBRY GENETICS

14-1361, -1366

CERTIFICATE OF INTEREST

Counsel for the Plaintiffs-Appellants, University of Utah Research Foundation, The Trustees of the University of Pennsylvania, HSC Research and Development Limited Partnership, and Endorecherche, Inc. certifies the following:

1. The full name of every party or amicus represented by me is:

University of Utah Research Foundation, The Trustees of the University of Pennsylvania, HSC Research and Development Limited Partnership, and Endorecherche, Inc.

2. The name of the real party in interest represented by me is:

University of Utah Research Foundation, The Trustees of the University of Pennsylvania, HSC Research and Development Limited Partnership, and Endorecherche, Inc.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

None

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court are:

Parsons Behle & Latimer: David G. Mangum, C. Kevin Speirs, Kristine Edde Johnson, Michael R. McCarthy

Date: March 24, 2014

/s/ *David G. Mangum*

UNIVERSITY OF UTAH, et al. v. AMBRY GENETICS

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CERTIFICATE OF INTEREST

Counsel for the Plaintiff-Appellant, Myriad Genetics, Inc. certifies the following:

1. The full name of every part or amicus represented by me is:

Myriad Genetics, Inc.

The name of the real party in interest represented by me is:

Myriad Genetics, Inc.

2. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

None.

3. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court are:

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Parsons Behle & Latimer: David G. Mangum, C. Kevin Speirs, Kristine Edde Johnson, Michael R. McCarthy

Myriad Genetics, Inc.: Benjamin G. Jackson, Matthew Gordon

Date: March 24, 2014

/s/ *Jonathan E. Singer*

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Ex. C	Excerpts from the Declaration of Benjamin B. Roa, dated July 9, 2013
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INTRODUCTION

In the 1990s, Myriad and collaborating academic scientists made two groundbreaking discoveries that electrified the scientific community: they identified the chromosomal location and DNA sequences of two genes responsible for hereditary breast and ovarian cancer—the BRCA1 and BRCA2 genes. The discoveries even led the NBC Nightly News. Building on these breakthroughs, Myriad invested hundreds of millions of dollars to create innovative molecular diagnostic testing for hereditary breast and ovarian cancer that has revolutionized patient care and provided medical diagnostic and treatment options that were unavailable to patients before Myriad's efforts. These tests are covered by the inventions claimed in the patents-in-suit, which, contrary to popular media misconception, do not simply cover the isolated BRCA1 and BRCA2 genes.

Now, in the wake of *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013) ("*AMP*"), the Supreme Court decision concerning the patentability of isolated human genes, Ambry and other companies seek to free-ride off Myriad's work and offer their own infringing diagnostic tests. Myriad and its research partners, the University of Utah Research Foundation, The Trustees of The University of Pennsylvania, HSC Research and Development Limited Partnership, and Endorecherche, Inc. (collectively, "Myriad"), brought suit to stop this infringement and moved for a preliminary injunction in July 2013.

Although the district court correctly found that Myriad "likely will suffer irreparable harm without injunctive relief," the district court denied the motion because it incorrectly found a substantial question of invalidity under 35 U.S.C. § 101 where none exists. In reaching this result, the district court misinterpreted both the *AMP* and *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289 (2012) decisions from the Supreme Court, as well as this Court's decision in *Association for Molecular Pathology,* 689 F.3d 1303 (Fed. Cir. 2012), finding the reach of section 101 to be far broader than the Supreme Court and this Court have held.

Myriad has appealed the denial of a preliminary injunction and moves this Court, under Federal Rules of Appellate Procedure 2 and 27(a), for an order expediting this appeal. Counsel for Ambry has stated that they will oppose this motion. Under Myriad's proposed expedited schedule, the opening brief would be due April 18, the response May 19, the reply May 29, and the joint appendix May 30. An expedited schedule is appropriate here for several reasons. First, the district court has already found that Myriad will be irreparably harmed without an injunction, and any further delay in deciding this appeal furthers that harm as Ambry is free to sell its infringing tests. And because Myriad has filed infringement suits against numerous other defendants as well, and those cases are combined with the Ambry case in an MDL proceeding before the same district

court, the decision here likely affects Myriad's ability to obtain injunctive relief against any of those other defendants as well. Second, the patents-in-suit begin to expire in August 2014. Myriad waited eight months from the filing of its motion for injunctive relief for the district court to rule, and it cannot afford to wait any longer. Finally, Myriad is likely to prevail on the merits of this appeal because the district court's errors in the interpretation of section 101 are readily apparent, and it is critical to correct those errors quickly in this evolving area of law. Myriad therefore respectfully requests that this Court grant the motion to expedite this appeal.

ARGUMENT

A. An Expedited Appeal is Needed Because the District Court Found that Myriad would be Irreparably Harmed Without an Injunction, and the Patents Are Nearing Expiration

In detailed briefing and declarations, and over the course of three days of hearings, Myriad presented extensive evidence of irreparable harm. As befits its pioneering status, before Ambry announced that it would offer a competing test mere hours after the Supreme Court's decision in *AMP*, Myriad was the only company to offer a full sequence test for the BRCA1 and BRCA2 genes in the United States. Ambry is now not only offering a directly competing test that infringes Myriad's patents, but is doing so at a significantly lower price. (Ex. A (Dkt. No. 185) at 58.) As the district court properly found, Ambry's competing

test will likely force Myriad to lower its prices or lose market share. (*Id.* at 60.) Indeed, as an example, Myriad presented evidence that at least one of the third party payors who provides reimbursement for patients' use of Myriad's tests has already significantly reduced its reimbursement rate to Myriad. (*Id.*) The district court rejected Ambry's argument that Myriad could easily reverse this price erosion if Ambry's test is later forced off the market, finding that Myriad's expert had "persuasively note[d] that once prices drop, Myriad will face daunting resistance to reinstating higher prices." (Ex. A (Dkt. No. 185) at 60; Ex. B (Kearl Decl.) at 11-13.)

After reviewing and analyzing all the evidence, the district court found that Myriad had presented "logical and persuasive testimony" that it "will suffer irreparable financial harm if an injunction does not issue." (Ex. A (Dkt. No. 185) at 61; *see also id.* at 62, 65-66.) The court explained that damages are not adequate to compensate Myriad for any harm suffered as a result of Ambry's sales of competing BRCA tests because "complex pricing and sales factors in this case present a substantial danger that they will be undercompensated if they prevail on the merits," and because there are "serious concerns about Defendant's ability to pay a large damage award." (*Id.* at 67-68.) This Court has repeatedly found that the very type of facts found by the district court—price erosion, loss of market share, and loss of patent exclusivity—are persuasive and important in the analysis

of injunctive relief. *See, e.g.*, *Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1362-63 (Fed. Cir. 2008); *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1382 (Fed. Cir. 2006).

Yet, despite its clear findings that Myriad will be irreparably harmed in the absence of a preliminary injunction, the district court went on to deny the motion for a preliminary injunction. In light of the finding of irreparable harm, this appeal should be expedited so that the appeal can be resolved as soon as possible and, if Myriad prevails, the harm suffered by Myriad can potentially be lessened by the entry of an injunction.

Moreover, this appeal should be expedited because of the currently-pending infringement lawsuits against several other defendants in cases consolidated with the Ambry case in an MDL proceeding before the same district court. Any request by Myriad for injunctive relief to prevent further irreparable harm by these other defendants' sale of infringing tests is unlikely to be granted relief unless and until the district court's legal errors are corrected by this Court.

Lastly, the patents-in-suit begin to expire in August 2014. In recognition of this, Myriad filed its preliminary injunction motion on July 10, 2013, shortly after Ambry announced the launch of its infringing tests. The district court, however, did not issue its decision on the motion until March 10, 2014, eight months later. With the term of the patents nearing an end, a decision that corrects the district

court's errors as soon as possible is appropriate so that Myriad and its research partners are able to obtain the full benefit of the exclusive rights that are afforded by their inventions.

B. An Expedited Appeal Is Needed to Correct the District Court's Errors Under Section 101

The district court based its denial of Myriad's preliminary injunction motion on its finding that Ambry is likely to succeed in showing that the asserted claims are invalid under section 101. In making this finding, the district court made significant errors in its analysis of both types of claims at issue—the claims directed to methods of using the BRCA gene sequences and the claims directed to primer pairs for the BRCA gene sequences. Specifically, the court interpreted *Mayo* and *AMP* too broadly and set a standard for section 101 that is nearly impossible for any DNA-related claim to meet.

In *AMP*, the Supreme Court, favorably referring to Judge Bryson's opinion concurring-in-part and dissenting-in-part in this Court's earlier opinion in that case, explained that specific applications of a natural product are patent-eligible subject matter: "Judge Bryson aptly noted that, '[a]s the first party with knowledge of the [BRCA1 and BRCA2] sequences, Myriad was in an excellent position to claim applications of that knowledge. Many of its unchallenged claims are limited to such applications.'" *AMP*, 133 S. Ct at 2120 (quoting *AMP*, 689 F.3d at 1349). Asserted claim 7 of the '441 patent-in-suit is remarkably similar to the specific

claims that Judge Bryson identified as patentable applications of knowledge, in a decision that came ***after*** and specifically analyzed the *Mayo* decision. For example, claim 7 and claim 21 of the '441 patent, which was one of the unchallenged claims that Judge Bryson indicated would be patentable, cover specific applications of the BRCA1 gene that involve comparing a human BRCA1 sample with a wild-type BRCA1 sequence using specific laboratory techniques and synthetic DNA probes and primers, as shown below:

'441 patent claim 7	'441 patent claim 21
7. The method of claim 1 wherein a germline nucleic acid sequence is compared by ***hybridizing*** a BRCA1 gene probe which specifically hybridizes to a BRCA1 allele to genomic DNA isolated from said sample and ***detecting*** the presence of a hybridization product where a presence of said product indicates the presence of said allele in the subject.	21. The method of claim 30 wherein a germline alteration is detected by ***hybridizing*** a BRCA1 gene probe which specifically hybridizes to an allele of one of said alterations to RNA isolated from said human sample and ***detecting*** the presence of a hybridization product, wherein the presence of said product indicates the presence of said allele in the sample.

This type of specific, limited application of BRCA1 knowledge is patentable under § 101.

The district court, though, ignored the similarities between the asserted method claims and the claims that Judge Bryson indicated would be patentable applications of knowledge, instead comparing the asserted claims to the claims that this Court ***invalidated*** in *AMP*, erroneously finding them to be "striking" in their similarities. (Ex. A (Dkt. No. 185) at 90.) But, unlike claim 7, those invalidated

method claims were found patent ineligible because they covered only "abstract mental processes"—specifically, they recited abstract methods for comparing or analyzing gene sequences without reciting any physical steps. Claim 7, by contrast, expressly recites specific physical steps, namely "hybridizing" and "detecting" (claim 7). The district court's comparison to the invalidated method claims was inappropriate and indicative of its flawed analysis.

The district court then went on to discuss the asserted method claims under *Mayo* and made further serious errors. According to the district court, "[a]side from the patent-ineligible, naturally occurring sequence of the BRCA1 and BRCA2 genes, the other steps set forth in the Method Claims are conventional activities that were well-understood and uniformly employed by those working with DNA at the time Myriad applied for its patents." (Ex. A (Dkt. No. 185) at 94.) In breaking up the claims this way, the district court violated the long-standing rule from *Diamond v. Diehr*, 450 U.S. 175, 189 (1981), that "[i]n determining the eligibility of respondents' claimed process for patent protection under § 101, their claims must be considered ***as a whole***. It is inappropriate to dissect the claims into old and new elements and then to ignore the presence of the old elements in the analysis."

The district court has done exactly what the Supreme Court in *Diehr* said was inappropriate—ignored the supposedly natural sequence in its entirety and

simply looked to the other steps in the claim in the abstract. *Mayo* does not instruct the court to do this type of analysis, as the district court erroneously appeared to believe. Rather, *Mayo* explains that the claims at issue there were invalid because they merely "inform a relevant audience about certain laws of nature; any additional steps consist of well-understood, routine, conventional activity already engaged in by the scientific community; and those steps, ***when viewed as a whole***, add nothing significant beyond the sum of their parts taken separately." 132 S. Ct at 1298 (emphasis added). The district court improperly failed to view the steps of the claim as a whole.

When asserted claim 7 of the '441 patent is viewed ***as a whole***, without simply ignoring the DNA sequences, it is clear that it recites more than "routine," "conventional" steps previously used in the art at the time of Myriad's patent applications. Indeed, the BRCA1 sequence was unknown at the time of the inventions, and the hybridization and detection steps recited in claim 7 using primers specially designed for the BRCA1 gene were not previously performed in the art and, rather than being routine or conventional, were unknown. In contrast, the invalidated *Mayo* claims were directed to a method involving a ***known*** drug metabolite used as a ***known*** biomarker, using the same assays that had been performed in the very same way on that same biomarker for years in the prior art.

The district court's analysis of the primer pair claims similarly suffers from significant errors. The majority of the court's analysis is directed to concluding that the Supreme Court in *AMP* did not find that all synthetic DNA is automatically patent-eligible. (Ex. A (Dkt. No. 185) at 82.) The district court, however, gave significantly less analysis to the more important question of whether the asserted claims directed to primer pairs—for example, claims 16 and 17 of the '282 patent—were patent eligible as unique combinations that do not exist in nature.

Claims 16 and 17 are directed to ***pairs*** of single-stranded primers, which do not occur in nature. These pairs of primers are structurally and functionally different than naturally-occurring DNA. First, these primer pairs contain two discontinuous pieces of DNA from separate strands and different locations along the full DNA strand. (Ex. C (Roa Decl.) ¶¶ 20, 6.) This "pair" of DNA strands cannot be found, as claimed, in nature. Second, whereas naturally-occurring genomic DNA necessarily contains biological information for the coding of proteins, the claimed primer pairs contain none of this information and cannot perform the same function as genomic DNA, which is to code for protein expression. (Ex. D (Kay Decl.) ¶¶ 16-18, 21-30; Ex. C (Roa Decl.) ¶¶ 6-0, 16-19.) Instead, primer pairs perform an entirely different function that has no analog in

nature—acting in concert to start the PCR chain reaction process of creating synthesized DNA in the laboratory. (*Id.*)

The district court erroneously found that the PCR-related function of the primers was not "markedly different" and not sufficient to make the primer pairs patentable because "primers function like natural DNA during replication" and "PCR with primer pairs exploits this natural DNA function to a useful end." (Ex. A (Dkt. No. 185) at 87.) But the use of primer pairs to adapt a DNA replication function to a particular useful end is just the type of invention that is patentable under the standards set forth in *Diamond v. Chakrabarty*, 447 U.S. 303 (1980). The primer pair claims are plainly not an attempt to patent the natural DNA itself. Under the district court's flawed analysis, any claim that involved a specific, practical use of a natural DNA function would be unpatentable. This broad rule is not supported by any of the reasoning in *AMP*.

It is important that the district court's errors concerning the section 101 analysis be corrected as quickly as possible, not only because they are critical to the case between Myriad and Ambry, but also to all the cases that have been consolidated before this same district court under the MDL. Moreover, as this area of law is quickly evolving and changing, this Court's swift guidance is especially important.

C. Proposed Schedule for Appeal

For the reasons above, Myriad respectfully requests the following expedited briefing schedule, which allows the parties each 30 days to file their principal briefs and does not allow for any extensions of time.

Event	**Deadline Set by Court Rules**	**Proposed Expedited Schedule**
Appellants' Blue Brief	Within 60 days after docketing (May 19)	30 days after docketing (April 18)
Appellee's Red Brief	Within 40 days after Appellants' blue brief is served	30 days after the blue brief is served (May 19)
Appellants' Grey Brief	Within 14 days after Appellee's red brief is served	10 days after the red brief is served (May 29)
Joint Appendix	Within 7 days after the last reply brief	11 days after the red brief is served (May 30)

Myriad submits that its proposed schedule is reasonable. In other cases involving grants or denials of injunctions, this Court has imposed an expedited schedule of as little as 14 days. *See, e.g.*, *Eli Lilly & Co. v. Actavis Elizabeth LLC*, 2010 WL 3374123 (Fed. Cir. Aug. 26, 2010).

In addition to the expedited briefing, Myriad also respectfully requests that the Court schedule oral argument for this appeal on the earliest possible date after completion of the briefing that the Court's schedule will accommodate. Myriad further requests that the Court expedite its disposition to the extent consistent with thorough consideration of the issues.

CONCLUSION

For the reasons set forth above, Myriad respectfully requests that the Court grant the motion to expedite the briefing and argument of this appeal.

Dated: March 24, 2014

Respectfully submitted,

FISH & RICHARDSON P.C.

/s/ *Jonathan E. Singer*

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Appeal from the United States District Court for the Central District of Utah in consolidated case no. 2:13-cv-00640, Judge Robert J. Shelby.

[PROPOSED] ORDER GRANTING MOTION TO EXPEDITE APPEAL

Good cause appearing, it is hereby ordered that Appellants' Motion to Expedite Appeal is granted. Appellants' opening brief will be due April 19, 2014. Appellee's responsive brief will be due May 19, 2014. Appellants' reply brief will be due May 29, 2014. The joint appendix will be due May 30, 2014.

March ____, 2014 By: _____

CERTIFICATE OF CONFERENCE

I hereby certify that I have conferred with William Gaede, counsel for Appellee, Ambry Genetics concerning the filing of this motion. Appellees will oppose this motion.

/s/ *Jonathan E. Singer*

Attorney for Plaintiff-Appellant
MYRIAD GENETICS, INC.

CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Federal Circuit by using the appellate CM/ECF system on March 24, 2014:

1. Motion to Expedite Appeal;
2. Certificates of Interest; and
3. Proposed Order Granting Motion

I further certify that counsel of record are registered as CM/ECF users and will be served by the appellate CM/ECF system and via email:

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